

The Maryland Board of Pharmacy  
February 18, 1998  
Public Minutes

**Attendance:** David Russo, President, W. Irving Lottier, Secretary; Commissioners Stanton Ades, Wayne Dyke, George Voxakis, Dorothy Levi; Paul Ballard, Board Counsel; Norene F. Pease, Executive Director, David Denoyer, Pharmacist Compliance Officer and Carol Gibbs, Staff Secretary

**Absent:** Commissioner Rev. William E. Johnson, Sr.

**Guests:** Bob Landsman, CVS Pharmacy  
Michael Ahearn, Pyxis Corporation  
Raymond Love, University of Maryland-School of Pharmacy  
Nathan Gruz, Pharmacist  
Virginia Camaelot, JHU Student  
Anne Marie Simons, JHU Student  
Sergie Nicastrì-JHU School of Public Health  
Melvin Rubin, Halethorpe Pharmacy  
Jack Freedman, Drug Control  
Robert J. Boerner, MPHA

Chair David Russo called the Public Session of the Board Meeting to order at 8:45 AM

**1. Record of Conflict of Interest**

David Russo began the Public Session with the first order of business, asking if any Board member present had any conflict of interest with any agenda item. For the record, there were no conflicts of interest pertaining to the February Public Agenda items.

**2. Minutes**

David Russo asked if there were any changes to the January, 1998 minutes. Barbara Jackson made a motion that was seconded by Stanton Ades seconded to approve the minutes and all Board members unanimously agreed.

**3. Reciprocity**

Wayne Dyke met with nine (9) candidates on February 17, 1998, all of whom were applying for reciprocity. The reciprocity candidates are listed as follows:

Nerissa E. Banks

Anketse Endeshaw

**Paula D. Fry\***  
Hannah N. Njonjo  
**Stephen O. Ohimor\***  
Kimberly A. Sprenkel

Kayode C. Jacobs  
**Kenneth I. Ochulor\***  
Wesley Roberts

Wayne Dyke made a motion to approve all reciprocity candidates for licensure with the exception of the three (3) candidates who need to be tested for oral English competency. Barbara Jackson-Faltz seconded the motion and all Board members unanimously agreed. (\*indicates candidates needing to complete oral English competency)

#### **4. Executive Director's Report**

##### **A. Update of Board/Poison Information Center Media Campaign**

Norene Pease, Tamarra Banks and George Voxakis from the Board and other members of the Oversight Committee met with representatives from MMA Media Consultants about the Maryland Poison Information Center Media Campaign on February 17, 1998. The discussion centered on the review of creative slogans for posters and other communications tools for the media campaign. The slogan "Toxsense" will be introduced to the public conveying the message to stay free from dangerous toxins.. Free air time for radio and possible television messages will be sought by MMA. MMA plans to launch the campaign during National Poison Prevention Week which runs March 16-22, 1998. The Board of Pharmacy will be credited for sponsoring the prevention messages.

##### **B. MPhA/MSHP Mid-Year Booth Sponsorship**

MPhA/MSHP mid-year meeting will be held Saturday, February 28 through Sunday, March 1, 1998 at the Sheraton Baltimore North Hotel in Towson. The exhibit hall containing the Board's information booth will be held from 11:30 AM to 2:00 PM on March 1, 1998. Board members George Voxakis, Barbara Jackson-Faltz, Irving Lottier and David Russo volunteered to staff it. The Board will distribute Maryland State shaped magnets which will include the board phone, fax and toll free numbers.

##### **C. NABP Workload Systems Task Force**

Norene Pease attended the NABP Workload Systems Task Force on January 23-24, 1998. Ms. Pease was asked to sign a Confidentiality Agreement prior to participation in the Task Force. The confidentiality agreement ensures that Ms. Pease does not reveal the details of the

Committee discussion prior to the NABP Committee Report at the annual meeting in May 1998. Ms. Pease stated that she was happy to learn that the Committee did not favor an approach of managing workload systems by establishing pharmacist workload or staffing quotas. Rather the Committee was considering an approach that would establish methods for pharmacies to participate continuous quality management programs to study when and how errors occur and what actions to take at the individual pharmacy store level to avert them.

**D. NABP 94th Annual Meeting-May 16-20, 1998**

NABP 94th Annual Meeting is scheduled for May 16-20, 1998 at the Hilton at Walt Disney World Village in Orlando, Florida. This year's meeting, "Pharmaceutical Competence: The Dream; The Vision; The Reality," include topics such as the growing popularity of alternate medical therapies; how the FDA's new fast track drug approval process fared in its handling of anti-obesity medication; continued competence for lifelong pharmacy practice; and how the computer glitch predicted for the year 2000 will affect NABP and the board offices. Boards' compliance officers will be offered a special CE track, which will look at pharmacy self-inspection programs and instructions for getting the most out of the Internet. The deadline for registration is May 1, 1998.

There were no members of the Board who indicated they were available to attend the conference, consequently a motion was made by George Voxakis and seconded by Irving Lottier to delegate Norene Pease as the Board's voting delegate to the annual conference and for David Denoyer to serve as the alternate. The motion included the recommendation that the budget item for funding for two Board representatives to attend the conference be utilized by Norene Pease and David Denoyer. The motion was unanimously adopted.

**E. Relocation to Spring Grove**

The Board plans to move to the Spring Grove Hospital Center tentatively in August 1998. Representatives from the Board met with Guy Basham from Spring Grove to view the Bland Bryant Building and to discuss potential renovations. A space allocation request has been submitted to the Department for review. The Board of Physician Quality Assistance, the Occupational Therapy, the Dental and Pharmacy Boards have also indicated to the Department interest in moving to the Center. The Board may want to consider utilizing unspent funding appropriated for the NAPLEX to cover the costs of renovation.

**F. BPQA Meeting on Delegation of Duties to Medical Assistants**

Norene Pease and David Denoyer attended a meeting with the Board of Physicians Quality Assurance on February 26, to participate in the discussion of delegation of medical duties to medical assistants. Nursing Organizations expressed concerns about medical assistants who are utilized in a non-hospital setting who do not have any special education to perform required duties, and where there are no consistent written standards of practice. Medical assistants routinely call in prescriptions. The nurses who testified stated that doctors should be concerned with unlicensed persons performing duties that a physician's assistant or nurse practitioner needs special training and licensure to perform.

The Board of Physician Quality Assurance referred the issue to its Physician Practice Committee for further consideration and redrafting of the preliminary regulation. It is anticipated that the next iteration of the regulation will not be available for review until May 1998. Board of Pharmacy staff will receive notice of the Practice Committee meetings and will continue to track this issue.

**G. Nursing Declaratory Ruling-Pharmacists**

The Nursing Board's Declaratory Ruling on acting on verbal orders ( oral or telephone ) or on a modified written medication order currently reads that a nurse may only act on verbal orders transmitted through a third party or on a written medication order modified by a clinical Pharm.D, licensed pharmacist. There is no such category of licensed pharmacist. The Board has provided additional information to the Board of Nursing and has requested that the Board of Nursing reconsider their Declaratory Ruling. To date the Board of Nursing has not taken any action to revise its ruling.

**H. State Ethics Commission**

The State Ethics Commission has determined that the Pharmacy Review Committee ( Peer Review ) and its members that was established in the revisions to Title 12 that became effective October 1, 1997 are exempted from the requirements to file the annual limited board and commission financial disclosure statement. This only applies to the financial disclosure requirements, other sections of the Ethics Law continue to apply to members of the Committee.

**I. National Public Radio-Washington Post**

An article published in the Sunday, February 15, 1998 Washington Post indicated that two large pharmacy chains doing business in Maryland were releasing confidential patient prescription data to third parties. The medical benefit to patients regarding this practice was called into question by the Post. The Board has reviewed requests to release confidential patient prescription data to third parties in the past and is on the record recommending that patients must be informed about the type of information that they agree to have released and must sign a written statement indicating that they are waiving their right to maintain the confidentiality of prescription data with the pharmacy or group of pharmacies with whom they conduct their prescription business.

#### **J. Budget Hearings**

The legislative analyst has recommended cutting \$ 520,000 from the Budget Program that encompasses the sixteen health occupations boards and the Kidney Commission. Significant cuts were also recommended for BPQA. All Boards plan to argue that the cuts should not be taken. The Legislative Analyst is using, in part, an argument that the Boards have not completely spent their FY 1996 and 1997 appropriation which indicates that the Boards do not need all of the funds that are appropriated. The Boards state that there are circumstances specific to each Board that determine why certain funds are not spent each year. The analyst was also concerned about the total reserve fund for all of the Boards and the Commission and suggested that each Board should report its plan for what is an appropriate reserve amount to maintain and how the Board plans to achieve an appropriate target amount for the reserve fund.

### **5. Board Counsel's Report**

#### *Due Process Considerations Relating to Prospective Continuing Education Audits-Letters to Licensees - Explaining the Process*

The letter of notice of intent to deny license renewal to licensees who failed to provide the required CE during their renewal period drafted by Board Counsel was reviewed by the Board. The letter indicates that licensees have a right to a hearing to show cause why they believe that they have either met the continuing education requirements for renewal or that circumstances beyond their control have rendered them from completing the requirements prior to denial of renewal of the license. The licensee has a right to a hearing if the renewal application was received two weeks or more before the last day of the renewal period. Pharmacists completing the renewal application during this time frame will be able

to continue to practice until the time of the show cause hearing. Conversely, if the licensee has not attempted to complete the renewal process two weeks prior to the end of the renewal period, they will not be entitled to continue to practice until the time of the hearing.

One noted change was made to the letter in paragraph 7, line 1; it now reads: “**Because** you filed your application for renewal of your license at least .....”. Changed to read: “**If** you filed your application for renewal of your license at least.....” Stanton Ades moved to accept letter with noted change and Barbara Jackson-Faltz seconded the motion. All Board members agreed to accept the letter with the change.

#### *HB267 and Conflict with Federal Law*

HB 267 would allow a pharmacist to administer medication, such as influenza vaccines, to individual patients on a blanket *order* from a prescriber. An *order* does not individually identify the patient. However, 21 USC §353 requires that some medications (like influenza vaccine) not be dispensed unless a *prescription* exists for the medication. A *prescription* does identify the individual patient. Thus, when HB authorizes a pharmacist to administer such a drug without a prescription it is technically in violation of Federal law.

However, because of the provision within HB 267 requiring that a pharmacist not administer such a drug on an *order* unless it was dispensed for immediate administration, HB 267 is probably consistent with, at least, the spirit of the Federal law.

Board counsel will research how nurses currently perform similar functions without violating the Federal law.

## **6. Task Force/Strategic Planning Reports**

Commissioner George Voxakis reported on the Strategic Planning Committee meeting which was held on January 26, 1998. The Task Force agreed to narrow the Collaborative Practice Bill to address the following collaborative situations: asthma, diabetes, hypertension, hyperlipidemia, anticoagulation therapy and pain and nausea management. These are the categories of drug therapy management where pharmacists have had the most documented evidence of success in improving health outcomes. There were several other provisions in the Collaborative Practice Bill that were streamlined in an effort to make it shorter, more easily understood and acceptable to pharmacy groups and allied health professionals.

A hearing on HB 267 - Administration of Drugs is scheduled for Tuesday, February 24, 1998 in Annapolis. The Strategic Planning group will meet prior to the hearing in order to organize testimony for the hearing.

Former Board Member Melvin Rubin reported on his research regarding the criteria the Board could use to determine certification of pharmacists to administer medications. Mr. Rubin has been working with Dr. Robert Kerr at the School of Pharmacy who chairs the Curriculum Development Committee. The Committee has examined requirements for students at the school for engaging in medication administration. The Pharmacy School has indicated that clinical theory related to medication administration is currently in the curriculum. A three week course to teach technical administration skills will be added to the curriculum. The University of Maryland, Nursing School has indicated that they are willing to provide instruction on the technical skills associated with medication administration to pharmacy students.

The school will develop a course of study for licensed pharmacists to take that would lead to certification to administer granted by the Board. The course would include passing a practical examination of technical skills demonstrating the pharmacist is competent to administer using various methods.

## **7. Committee Reports**

### **A. Licensing Committee**

There was no report from the Licensing Committee

#### **MPhA Request for Clarification on the Granting of Continuing Education Credits**

The Maryland Pharmacist Association will hold its mid-year meeting on February 28, and March 1, 1998 which falls into two months. Robert Boerner inquired if the Board would consider the credits for both days for persons who were due to renew their license in February? There was lengthy discussion of the question and the Board determined that registrants for the mid-year conference should indicate to MPhA if they needed credits for February or for March. MPhA would issue separate certificates for each day. Certificates issued for February 28, 1998 may be used for continuing education credits due for those licensees renewing in February and March 1, 1998 certificates may be used as CE credits for those licensees who are due to renew in March 1998. Registrants must request in advance in which month they want the certificate dated.

B. Legislative Committee - Positions on 1998 Legislation

1. Pharmacy Support Personnel-Delegate Goldwater's Legislation:  
HB 765 -Task Force on Pharmacy Technicians

An amendment to the Bill establishing a Task Force to study the use of Pharmacy Technicians in Maryland will be offered by Delegate Bozman. The amendment addresses increasing participation on the Task Force from eight to ten members. The hearing on the Bill is scheduled for March 3, 1998. It was recommended that the Board support the Bill with the amendment to add two members of the Board to the Task Force. Barbara Faltz Jackson moved to accept the recommendation which was seconded by Stanton Ades. All Board members voted unanimously to accept.

2. House Bill 139-Unspent Special Funds-Waiting List Equity Fund

This Bill targets ninety percent of Boards project reserve funds to be dedicated to provide community services for the developmentally disabled. This bill is scheduled for a hearing on March 3, 1998. The Boards and the Commission all intend to oppose this Bill. Dr. Guy Champaine, a Board member with the Dental Board, agreed to testify on a panel to oppose the Bill. George Voxakis volunteered to act as back up to Dr. Champaine. Barbara Faltz Jackson made a motion seconded by George Voxakis to oppose HB 139. All Board members unanimously approved.

3. House Bill 383 - Disclosure of Information

House Bill 383 requires that health occupations boards disclose information regarding possible insurance fraud in their records to the Insurance Fraud Division of the Maryland Insurance Administration. Several Health Professional Boards' joint position on the Bill is that the Bill should be supported with an amendment indicating that the information pertaining to fraud cases may, at the discretion of the Board, be forwarded to the Fraud Division. Barbara Faltz Jackson made a motion to accept this position and George Voxakis seconded the motion. All Board members unanimously agreed to accept it.

4. Senate Bill 412



## Consumer Protection-Drug Storage and Shipment Safety Act

This bill is being submitted for the purpose of authorizing the Board of Pharmacy to monitor the delivery of prescription drug orders to patients in Maryland when the potential exists for drugs to be exposed to temperatures that could alter the drugs efficacy. The Bill requires written notices to be placed in packages to notify recipients about the stability of the drugs that have been delivered.

George Voxakis made a motion which was seconded by Barbara Faltz Jackson to send a letter of support for the Bill including the amendments to be offered by Senator Bromwell. The letter of support should also indicate that the Bill language is placed in the correct section of Title 12, and require a separate 1-800- telephone number for non-resident pharmacies to establish in order to respond to patient inquiries about possible chemical degradation of delivered drugs. The motion passed unanimously.

### 5. HB444 Licensed Physical Therapists and Licensed Physical Therapist Assistants

The Board of Physical Therapy began working with the Board on the development of this Bill two years ago. The Physical Therapists seek authorization to procure, store and apply topical medications for their patients. The Board of Physical Therapy reviewed its Bill which failed during 1997 with the Board and the Board supported it. A similar Bill has been introduced in 1998. George Voxakis made a motion which was seconded by Barbara Faltz Jackson to write a letter of support for the Bill with the following amendment  
(G) IN CONSULTATION WITH THE STATE BOARD OF PHARMACY, THE BOARD SHALL ADOPT REGULATIONS CONCERNING THE STORAGE AND PROPER USAGE OF TOPICAL PHARMACEUTICAL AGENTS PROCURED UNDER THIS SECTION.

### 6. HB 803 Health Occupations - Boards - Project Reserve Funds

The sixteen Health Occupations Boards, the Commission, the Board of Physician Quality Assurance and the Board of Nursing requested that Senators Hoffman and Hollinger and Delegate Rosenberg introduce this bill authorizing the Boards to deposit up to fifty percent of any Board's annual appropriation in a reserve fund for the following limited purposes

unanticipated expenses relating to: duties created and mandated by the General Assembly, costs associated with the investigation or disciplining of licensees; or litigation expenses. Dorothy Levi made a motion which was seconded by Barbara Faltz Jackson to support passage of both the Senate and House Companion Bills. The motion was unanimously passed.

C. PEAC Update - Stanton Ades

No representative from PEAC attended the Board meeting. Stanton Ades reported that the following topics were discussed at the January PEAC meeting: how to address students with possible addiction problems, the PEAC presentation at the MPhA mid-year, and progress on the project to provide education and information to chain drug store on how to identify and report potential addiction problems with pharmacy staff.

D. Pharmacy Practice Committee

1. Report from February 11, 1998 meeting

During the 2/11/98 meeting of the Pharmacy Practice Committee, three issues were discussed: Emergency drugs and pharmacy automation; the Licensing and Certification Agencies' draft proposed assisted living regulations and proposed electronic transmission regulations, COMAR 10.34.20. The issue of the emergency drugs and pharmacy automation was discussed briefly and referred to the Board for a response.

2. Pharmacist Code of Conduct/Ethics

Commissioner Dorothy Levi submitted a revised version of the Pharmacist Code of Conduct/Ethics. This has been referred back to the Pharmacy Practice Committee for review at its next scheduled meeting on March 11, 1998.

3. Electronic Transmission Regulations

During the Pharmacy Practice Committee meeting of February 11, 1998, the proposed Electronic Transmission Regulations were discussed. Commissioner Levi composed a draft of the regulations. Ms. Levi's recommendation is to start with the prior Chapter, and add some new ideas from the last proposal and some of the comments received. The new proposal would incorporate a clause which states that a prescription would be considered a written

prescription in the definition section. The proposal would exempt institutional pharmacies from the certain requirements; and add a section requiring the permit holder to ensure that a system used has security system. The new proposal would require the permit holder to document the inquiries made to ensure the system is secure and confidential.

#### 4. Assisted Living Regulations

During the Practice Committee meeting, it was suggested that the Board respond to the draft proposal for Assisted Living Regulations that was developed by the Licensing and Certification Administration. With assistance from some pharmacists involved in assisted living services, it was suggested that the requirements include the following: the pharmacist should participate in the development of the curriculum for the medication management training programs; that the pharmacist should be the single representative responsible for medication oversight in the assisted living area; and that the prescriber writing the order for the patient is in the best position to determine whether the patient can self-medicate and should indicate on the prescription or call if the patient cannot self administer. Compliance Officer D. Denoyer will submit a letter after review by Commissioner Ades in response to the proposed regulations.

#### 5. Emergency Boxes

The Practice committee discussed the issue of the replacement of drugs in nursing homes which use automated systems as emergency and interim boxes. Mr. Denoyer stated that the main issue is who should be the pharmacists' representative putting drugs into the machine. A pharmacy employee or nursing staff could fill the machine. In response to a question, Mr. Michael Ahearn of the Pyxis Corporation spoke briefly about automated emergency boxes that are presently being used within long term care facilities. According to Mr. Ahearn, a nurse must access boxes in most facilities and not an assistant due to proper ID and security code, and in addition the name of the patient and medication must be entered with where medication is sent. To date, no report of an error involving emergency drugs and automated systems has been reported at a Maryland nursing home. Chair Russo stated that the Practice Committee should continue to monitor the practice and report any concerns to the Board.

E. Budget Committee - Tamarra Banks

1. Report from Budget Committee-2nd Quarter Projection

Tamarra Banks was absent and unable to present the 2nd Quarter Projections. President David Russo spoke on her behalf.

According to a preliminary report received from T. Banks, there are a few budget categories where the Board will exceed the allotted amount. Ms. Banks will prepare suggested policies for the Board to adopt at its March meeting to address these concerns. Ms. Banks wants to have appropriate policies in place so that the Legislative Auditors do not have concerns with spending in certain budget categories.

In general, the Board has at least \$50,000 to redirect from the NAPLEX Examination to other projects. Ms. Banks would like to spend as much of the budget appropriation as possible so as to avoid contributing additional money to the Board's reserve fund. Board members were reminded that HB 139 seeks to attach the Board's reserve funds for use by the developmentally disabled. Ms. Banks has suggested that some of the FY 1998 appropriation could be redirected to renovation for the future move to Spring Grove. Monies could also be utilized to purchase additional advertising for the media campaign.

F. End of Life Task Force-Stanton Ades

No new report from the End of Life Task Force

**10. Questions for the Board**

**A. Past Inquiry**

1. CLIA Regulations

Waiting for response from Pamela Owens on her research.

**B. New Inquiries**

1. Phone Orders for Nursing Declaratory Ruling Issue

Syncor Pharmacy Services inquired as to who is authorized to take prescription phone orders and can it be delegated. According to

the response submitted by D. Denoyer, taking prescription orders is considered "interpreting" prescriptions and is, therefore, practicing pharmacy under the Pharmacy Practice Act. This means support persons should not receive telephone prescriptions. Board members agreed that the response submitted was sufficient.

2. Pharmacist Presented with Two Prescriptions

The Board received an inquiry from CVS Pharmacy #1452 as to being presented with two (2) prescriptions for Ritalin, one for 30 units for school and another for 60 units for home. In order to save the patient money, the pharmacist proposed to combine the prescription and dispense 90 in one prescription bottle. This practice has been halted due to an inspection and subsequent written critique the Division of Drug Control. Mr. Denoyer and Mr. Freedman commented that to the DEA, the pharmacist should get a new prescription for the correct quantity. Another alternate would be to consider the second prescription a mistake and correct the quantity on the first prescription, therefore they may be combined. It would be up to the pharmacist to use their best discretion in these cases. The Board recommended that pharmacists do not combine prescriptions for Schedule II drugs.

3. Expiration of Stolen Drugs-Rock Creek Pharmacy

The Board received an inquiry from the Food and Drug Administration in reference to lot numbers and expiration dates being removed from stolen pharmaceuticals belonging to Rock Creek Pharmacy. According to an inspection report from FDA, the FDA seized all expired drugs

**11. Informational**

A. Pharmacy Receives Support from Influential Physician-Texas

B. Comments from FDA on "NTI" Drugs and Generic Substitution

After Legislative session, the Board will meet with the School of Pharmacy to discuss same.

C. Response to Environmental Matters on probation against a mail order company supplying a 90 supply of a Maintenance Prescription Drug

D. Drug Control improved inspection and investigation process

Jack Freedman and Bob Chang of the Division of Drug Control presented their views on the changes made to improve the inspection and investigation process to Board members. Of note, they would like to meet with the compliance officer every other Monday to review reports on previous inspections/investigations. Secondly, they would send out letters in reference to violations with notices to remedy violations within 14, 21 or 28 days with a response submitted to the Board after final inspection. If follow-up inspection is not done properly, a report will be submitted to the Board's Disciplinary Committee for review. Drug Control was invited to attend the Disciplinary Committee meetings that are held every two (2) weeks to review triage complaints.

Only inspection reports identifying a serious violation will be sent to the Board with a follow-up inspection report. The Board would like to include a comment section on the inspection report. Two suggestions were made: 1) The Board needs a sense of the cycle of inspection along with who conducted the inspection; and 2) reinforce who is working in the store as the pharmacist and report that information to the Board so that the Board knows where pharmacists are working should they need to be contacted.

The Board will work with drug control on maintaining a list of pharmacist whom the Board is trying to locate or who have not renewed their license and are still working.

Mr. Freedman invited Mr. Denoyer to meet with him to plan a method of prioritizing inspections. They will report to the Board after analyzing the most recent inspections.

The Public Session of the Board meeting adjourned for lunch at 12:15 PM and resumed at 1:05 PM, ending at 2:10 PM.

Respectfully submitted,

W. Irving Lottier, P.D.

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Board Secretary

